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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,973	08/09/2001	David Bilyeu	RTI-145	4358

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EXAMINER	
JARRETT, RYAN A	

ART UNIT	PAPER NUMBER
2125	6

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,973	BILYEU, DAVID	
	Examiner	Art Unit	
	Ryan A. Jarrett	2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the limitation "said one or more **template** designs" in line 1. There is insufficient antecedent basis for the limitation “template” in the claim.

Claim 19 recites the limitation "said sorted tissue" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 32 recites the limitation "said container" in line 17. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-18, 20-22, 25, 29, and 33-35 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Guzik US 2002/0091441 (see paragraphs 3, 4, 31, 33, 34, 36, 38, 39, 43-46, 49, 57, 63-65, 67, 69, 80, 84-90, 93, 94, 98, 99, 101, 102, 104, 108 and Figs. 7-10).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guzik as applied to claim 5 above. Guzik does not specifically disclose that the tissue sample is disposed in a sterilizing chamber during the scanning step or that the tissue sample is transferred between individual steps in sterilized containers.

However, Guzik does disclose maintaining the tissue sample in a hydrated state throughout processing in order to prevent undesirable and irreversible structural

changes, the hydrated state being maintained by a fluidized bed, a spray means, or submerging the tissue in liquid [0043]. Guzik also discloses sterilizing the tissue before and after cutting [0033] and storing the tissue sample in a sterilized sealed container [0122]. Based on these teachings, it would have been obvious to one having ordinary skill in the art to modify Guzik to maintain the tissue sample in a sterilized state throughout processing, including the scanning step and the transferring steps, if the pre-cutting and post-cutting sterilization steps taken by Guzik were not adequate enough to maintain and produce a sterilized tissue implant for use in a human being.

In this case, "sterilized state" means submersing or surrounding the tissue with a sterilizing agent by means of a container or chamber. It would have been obvious to modify Guzik in this fashion since Guzik discloses means for maintaining the tissue in a hydrated state throughout processing and since Guzik discloses the use of sterilized, sealed containers for storage. The fluidized bed and sprays of Guzik could be easily modified to contain a specific sterilizing agent instead of a general-purpose "hydrating agent".

8. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guzik as applied to claim 22 above. Guzik discloses inspecting the tissue product for quality verification [0099]. Guzik does not specifically disclose that the inspection is conducted by optical inspection cameras. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Guzik in this fashion since it is well known to use optical cameras to inspect tissue implants or

workpieces of any kind. Optical cameras provide a quick, accurate, and automated inspection and eliminate the possibility of human error.

9. Claims 26 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guzik as applied to claims 25 and 29 above. Guzik does not specifically disclose sterilizing the tissue implants by irradiation or that package sterilization is achieved through Sterrad sterilization procedures. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Guzik in this fashion since irradiation and Sterrad are well known, efficient, and effective means of sterilizing a tissue sample.

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guzik as applied to claim 5 above, and further in view of Yoshida et al. U.S. Patent No. 6,438,445. Guzik does not disclose directing the tissue sample to a specific machining device selected from a plurality of machining devices. However, Yoshida et al. discloses optimally selecting a machine tool for a workpiece in accordance with various input data, including the machining pattern data (col. 2 lines 1-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Guzik with Yoshida et al. since Yoshida et al. teaches that in this type of approach, a machining area and machining steps high in production efficiency can be selected, and the tools, machining conditions, and tool path most suitable for the input patterns can be determined.

11. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guzik in view of Yoshida et al. Guzik discloses an automated tissue processing system

comprising: at least one scanning device [0038] interfaced with at least one computer system enabled by at least one analytical software program and a database comprising a plurality of template designs [0036]; a cutting device for cutting a tissue sample into a desired blank [inherent in Fig. 5A #252]; an inspection station for inspecting the quality of the implant [0099]; a packaging station for packaging and labeling accepted tissue implants [0124]-[0126]; and a storage station for storing tissue implants prior to shipment [0124]-[0126].

Guzik does not specifically disclose a routing device for routing the tissue blank to an appropriate milling machine selected from a plurality of milling machines. However, Yoshida et al. discloses optimally selecting a machine tool for a workpiece in accordance with various input data, including the machining pattern data (col. 2 lines 1-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Guzik with Yoshida et al. since Yoshida et al. teaches that in this type of approach, a machining area and machining steps high in production efficiency can be selected, and the tools, machining conditions, and tool path most suitable for the input patterns can be determined.

Guzik as modified by Yoshida et al. does not specifically disclose a sterilization "chamber". However, Guzik does disclose sterilizing the tissue sample before and after cutting [0033]. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to sterilize the tissue sample of Guzik v. Yoshida et al. in a "chamber" in order to fully submerse and surround the tissue sample with the sterilizing agent, thereby maximizing the effectiveness of the sterilization process.

Guzik as modified by Yoshida et al. does not specifically disclose a "holding chamber" for holding rejected tissue samples. However, Guzik does disclose inspecting and discarding any tissue samples that appear to be damaged or calcified [0099]. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to discard the rejected tissue samples of Guzik v. Yoshida et al. into a "holding chamber", such as trash receptacle, in order to easily dispose of the rejected samples. Alternatively, it would have been obvious to use a "holding chamber" so that the rejected samples could be later examined in order to determine the cause of the defect.

12. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guzik in view of Yoshida et al. Guzik discloses an automated process for manufacturing implantable tissue products comprising: selecting a tissue sample for processing and sterilizing the tissue sample [0033]; transferring said sterilized tissue sample into an optimizer unit, wherein said tissue sample is scanned to obtain dimensional data corresponding to said tissue sample [0038]-[0039]; inputting dimensional data from said sample into a computer system enabled with an analytical software program and a database comprising a plurality of designs; analyzing said dimensional data with said analytical software program to identify a design type and quantity thereof commensurate with the dimensions of said tissue sample to maximize tissue utilization [0036], [0088]; routing said tissue sample into a cutting machine wherein said tissue sample is cut into a tissue blank of sufficient size and shape to facilitate subsequent machining of said tissue product according to said design [inherent in Fig. 5A #252];

milling said tissue blank [0040]-[0043] to produce a finished product in accord with said identified template design and quantity thereof; analyzing said finished product for quality [0099]; packaging and labeling said finished product and sterilizing said packaged product prior to storage [0124]-[0126].

Guzik does not specifically disclose placing the tissue blank into a sorter, wherein the blank is routed to an optimal milling device enabled to machine a design from the tissue blank in accord with the identified design and quantity thereof. However, Yoshida et al. discloses optimally selecting a machine tool for a workpiece in accordance with various input data, including the machining pattern data (col. 2 lines 1-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Guzik with Yoshida et al. since Yoshida et al. teaches that in this type of approach, a machining area and machining steps high in production efficiency can be selected, and the tools, machining conditions, and tool path most suitable for the input patterns can be determined.

Guzik as modified by Yoshida et al. does not specifically disclose that the individual cutting machine(s) or scanning devices are "sterilized". However, Guzik does disclose maintaining the tissue sample in a hydrated state throughout processing in order to prevent undesirable and irreversible structural changes, the hydrated state being maintained by a fluidized bed, a spray means, or submerging the tissue in liquid [0043]. Guzik also discloses sterilizing the tissue before and after cutting [0033] and storing the tissue sample in a sterilized sealed container [0122]. Based on these teachings, it would have been obvious to one having ordinary skill in the art to modify

Guzik v. Yoshida et al. to maintain the tissue sample in a sterilized state throughout processing, including the scanning step and the cutting steps, if the pre-cutting and post-cutting sterilization steps taken by Guzik were not adequate enough to maintain and produce a sterilized tissue implant for use in a human being.

Guzik as modified by Yoshida et al. does not specifically disclose storing the sterilized tissue implant for at least twenty-four hours. However, it would have been obvious to one having ordinary skill in the art to store the sterilized tissue implant for at least twenty-four hours in order for the implant to attain a sufficient level of sterilization by remaining in the container for a designated minimum length of time.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Moermann et al. U.S. Patent No. 4,575,805

Grooms et al. US 2002/0052605

Jansen U.S. Patent No. 6,528,006

Mills et al. U.S. Patent No. 6,613,278

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan A. Jarrett whose telephone number is (703) 308-4739. The examiner can normally be reached on 10:00-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard can be reached on (703) 308-0538. The fax phone number for the organization where this application or proceeding is assigned is (703) 746-7239.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

raj
11/20/03

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